IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

CHRISTOPHER TYLER LOFTON, Individually and on behalf of the ESTATE of CHRISTOPHER M. LOFTON, et al.,	§	
Plaintiffs,	§	
v.	§	Civil Action No. **3:05-CV-1531-L**
MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a Division of MCNEIL-PPC, INC., and JOHNSON & JOHNSON,	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the court is Plaintiffs' Motion for New Trial and/or Motion for Reconsideration of Ruling on Motion for Summary Judgment, filed February 5, 2010. After carefully considering the motion, response, record, and applicable law, the court **denies** Plaintiffs' Motion for New Trial and/or Motion for Reconsideration of Ruling on Motion for Summary Judgment.

I. Background and Procedural History

This case involves product liability claims relating to the over-the-counter drug Motrin. Plaintiffs Christopher Tyler Lofton, individually and on behalf of the estate of Christopher M. Lofton, and Sandy Lynn Lofton, as next friend for Tegan Lofton and Lauren Lofton, on their behalf and on behalf of the estate of Christopher M. Lofton (collectively, "Plaintiffs") brought claims of defective design, marketing defect, breach of express warranty, breach of implied warranty, negligence, and violation of the Texas Deceptive Trade Practices Act as a wrongful death action and

as a survival action. Plaintiffs assert claims against Defendants McNeil Consumer & Specialty Pharmaceuticals ("McNeil") and Johnson & Johnson ("J&J") (collectively, "Defendants").

On January 27, 2010, the court granted in part and denied in part Defendants' Motion for Summary Judgment. The court dismissed with prejudice Sandy Lofton's wrongful death and survival claims, Plaintiffs' marketing defect, breach of express warranty, negligence, and DTPA claims. In dismissing Plaintiffs' marketing defect, negligence, and breach of warranty claims, the court determined that Defendants were entitled to the rebuttable presumption pursuant to section 82.007(a) of the Texas Civil Practice and Remedies Code that the Motrin label was adequate.

Defendants originally filed their Motion for Summary Judgment on May 2, 2008. The parties jointly moved to abate these proceedings pending the decision by the Supreme Court in *Wyeth v. Levine*, 552 U.S. 1161 (2008). The court administratively closed the case on July 30, 2008. The Supreme Court reached its decision in *Wyeth* on March 4, 2009. 555 U.S. ___, 129 S. Ct. 1187 (2009) (hereinafter, "*Wyeth*"). The parties subsequently moved to reopen the case, and the court reopened the case on July 30, 2009. The court gave the parties an opportunity to file supplemental briefs regarding the effect of *Wyeth* on the pending motion. Plaintiffs and Defendants both filed supplemental briefs, and the court ruled on the Motion for Summary Judgment on January 27, 2010.

Plaintiffs now ask the court to reconsider its decision to dismiss with prejudice their claims for marketing defect, breach of warranty, and negligence. They argue that the decision in *Wyeth* precludes the court's decision with respect to those claims. Defendants oppose the motion, and Plaintiffs did not file any reply in support of their motion.

II. Legal Standard

Plaintiffs move for a new trial or for reconsideration of the court's January 27, 2010 memorandum opinion and order, but they do not cite the legal basis for their motion. Defendants respond that the court should apply the standard of Rule 59(e) of the Federal Rules of Civil Procedure in considering the motion and that Plaintiffs have failed to meet that standard. The court finds that Rule 59(e) does not apply because it has not yet entered judgment. It does, however, have the inherent power to revise or reconsider its orders. *Melancon v. Texaco, Inc.*, 659 F.2d 551, 553 (5th Cir. 1981); *see also Enlow v. Tishomingo County, Miss.*, 962 F.2d 501, 507 n. 16 (5th Cir. 1992) ("As this Court has repeatedly said, the district court has broad discretion in controlling its own docket. In fact, the district court may reconsider a previously denied summary judgment motion even in the absence of new material presented.") (internal quotations, brackets, and citations omitted). In light of the court's ability to reconsider its own interlocutory orders, it turns to Plaintiffs' arguments.

III. Analysis

Plaintiffs argue generally that the Supreme Court's decision in *Wyeth* requires reconsideration of the court's decision that the fraud-on-the-FDA exception to the statutory presumption is preempted by federal law. Much of their motion simply repeats verbatim sections of their original response to the Motion for Summary Judgment and their supplemental brief. To the extent that Plaintiffs simply repeat the arguments that were already considered, the court will not reconsider them, as Plaintiffs do not even attempt to make a new argument but simply reurge the same argument. Plaintiffs' argument that *Wyeth* affects the court's decision about the fraud-on-the-FDA exception is largely a new argument, and so the court will consider it.

Plaintiffs contend that *Wyeth* held that "state law tort warnings claims in pharmaceutical cases are not pre-empted by federal law, even where the labels are approved by the FDA, rejecting the drug company's claim that by approving a warning label, the state law warnings claims are impliedly preempted." Pls.' Brief (doc. 115) 2. They contend that the "logical extension" of this decision is that "any claims of federal preemption which affect a claimant's state common law tort rights for warnings should not be precluded either, including an exception which requires proof that the defendant failed to provide material and relevant information to the FDA . . . as is included in § 82.007(b)(1)." *Id.* Plaintiffs also distinguish the Texas fraud-on-the-FDA exception from the statute considered by the Sixth Circuit Court of Appeals in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), a case that this court explicitly followed in reaching its decision. Plaintiffs also urge the court to adopt the reasoning in the Second Circuit Court of Appeals decision in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff'd*, 552 U.S. 440 (2008). Plaintiffs argue that the court's decision prevents litigants in Texas from bringing common law marketing defect claims in Texas for drug-related injuries if the FDA approved the label. They contend that they have not brought a claim for fraud on the FDA, that the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2000), should not be extended to fraud-on-the-FDA exceptions to state statutory presumptions, and that there is evidence that Defendants withheld information from the FDA relating to Motrin.

Defendants contend that Plaintiffs have failed to meet the legal standard justifying reconsideration of the court's earlier order. They argue that Plaintiffs make the same arguments and present the same evidence that the court has considered and rejected. Because they contend that Plaintiffs have simply rehashed the same arguments made in prior briefing, Defendants stand on

their prior briefs as well. They contend that none of the evidence cited by Plaintiffs is newly discovered and that the court has already considered it.

The court has already stated that it would not consider the arguments advanced by Plaintiffs in their prior briefing, but Plaintiffs do make a new argument with respect to the effect of *Wyeth* on the court's holdings regarding section 82.007 of the Texas Civil Practice and Remedies Code. The court, however, is not persuaded that the application of *Wyeth* warrants any change to its prior decision on this issue.

The court's holding with respect to *Buckman* and the fraud-on-the-FDA exception was narrow. It held:

> The court finds that the concerns in *Buckman* hold true not only where a plaintiff brings a fraud-on-the-FDA claim but also where it seeks to show an exception to the presumption here. To avoid any intrusion upon the FDA's right to police fraud itself, the court follows *Garcia* and finds that section 82.007(b)(1) is preempted *in some circumstances, including as here, where Plaintiffs ask the court to reach the conclusion opposite of that reached by the FDA, that Defendants did not withhold information or mislead it.* Accordingly, the court finds that Defendants are entitled to the rebuttable presumption of section 82.007(a).

Mem. Order and Op. (Jan. 27, 2010) 20 (emphasis added). Its holding was limited to the facts before it, which included a specific finding by the FDA that "we have no evidence that there is additional undisclosed safety information that was withheld by ibuprofen manufacturers." *Id*. at 17 (quoting Defs.' App. 407).

The court's narrow holding in this case does not interfere with the application of *Wyeth*, in which the Supreme Court held that certain state law claims were not preempted by federal law. In *Wyeth*, the Court specifically rejected the argument that the FDA's labeling requirements were "both a floor and a ceiling," and held that a plaintiff could bring state law claims even where a drug bore

a warning label approved by the FDA. This holding, however, does not implicate the FDA's right to determine whether parties have committed fraud upon it, and the court maintains that Plaintiffs' claims, which are based upon an argument already rejected by the FDA, are preempted. The only claims that are barred by the court's holding are claims that assert fraud on the FDA that have already been considered and rejected by the agency. The court finds that, in those narrow circumstances, the Texas statutory exception to the rebuttable presumption should not apply because it risks creating a conflict between the court's possible findings and the FDA's conclusion. This holding does not otherwise affect the conclusion of the Court in *Wyeth* that plaintiffs may bring state claims even where the FDA approved the label.

To the extent that Plaintiffs argue that the court should follow *Desiano* in light of the *Wyeth* decision and that the statute in *Garcia* can be distinguished from section 82.007, the court also rejects these arguments. The court carefully considered authority from several courts when it determined the effect of *Buckman* on fraud-on-the-FDA exceptions to state statutory presumptions regarding drug labels. It accepted the view held by the majority of courts that *Buckman*'s rationale extends beyond state fraud-on-the-FDA claims to fraud-on-the-FDA exceptions to state statutory presumptions. As stated above, the court finds that its narrow holding should not be altered by the decision in *Wyeth*; it further finds that its reliance on *Garcia* and similar cases and rejection of *Desiano* also should not be altered.

For these reasons, the court determines that *Wyeth* does not provide a basis for reconsidering its earlier memorandum opinion and order. The court will not reverse its decision with respect to Plaintiffs' claims of marketing defect, breach of warranty, and negligence.

IV. Conclusion

For the reasons stated herein, the court **denies** Plaintiffs' Motion for New Trial and/or Motion for Reconsideration of Ruling on Motion for Summary Judgment**.**

It is so ordered this 17th day of June, 2010.

Sam A. Lindsay
United States District Judge